

Appl. No. : 10/698,320  
Filed : October 31, 2003

### AMENDMENTS TO THE CLAIMS

Please amend Claims 1, 4, 5, and 17 as follows:

1. (Currently amended) An aqueous ophthalmic gel formulation for the treatment of myopia comprising pirenzepine and an amount of gelling agent effective to form an aqueous gel, said gel having a Brookfield RVDV viscosity of from about 10,000 to about 300,000 cps at about 20°C and ~~sheer~~ shear rate of  $1 \text{ s}^{-1}$ , wherein said gelling agent is a water soluble cellulose derivative.
2. (Original) A formulation according to claim 1 wherein the concentration of said pirenzepine is from about 0.001 to 3 % (w/v).
3. (Original) A formulation according to claim 1 wherein the concentration of said pirenzepine is from about 0.005 to 2 % (w/v).
4. (Currently amended) A formulation according to claim 1 wherein said water soluble cellulose derivative is soluble in said aqueous formulation at a viscosity of about 15,000 to about 200,000 cps at about 20°C and ~~sheer~~ shear rate of  $1 \text{ s}^{-1}$ .
5. (Currently amended) A formulation according to claim 1 wherein said water soluble cellulose derivative is soluble in said aqueous formulation at a viscosity of about 100,000 cps at about 20°C and ~~sheer~~ shear rate of  $1 \text{ s}^{-1}$ .
6. (Original) A formulation according to claim 1 wherein said amount of gelling agent is an amount of from about 0.5 to 5 wt. %.
7. (Original) A formulation according to claim 1 wherein said amount of gelling agent is an amount of from about 1 to 5 wt. %.
8. (Original) A formulation according to claim 1, further comprising at least one member selected from the group consisting of sodium chloride, cetrimide, thimerosal, benzalkonium chloride, boric acid, sodium carbonate, potassium chloride, propylene glycol, polyoxyethylene, polyoxypropylene, polyoxyl 40 stearate, polyvinyl alcohol, poloxamer 188, sodium citrate, sodium thiosulfate, sodium bisulfite, dextran 70, acetic acid, polyethylene glycol, povidone, dextrose, magnesium chloride, alginate acid, sodium acetate, sodium borate, edetate disodium, sodium hydroxide, and hydrochloric acid.
9. (Original) A formulation according to claim 1 wherein said gelling agent is at least one member selected from the group consisting of hydroxypropyl methylcellulose, methyl

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cellulose, hydroxypropyl cellulose, carboxymethyl cellulose, hydroxyethyl cellulose, and cellulose gum.

10. (Original) A formulation according to claim 1 wherein said gelling agent is hydroxypropyl methylcellulose.

11. (Original) An ophthalmic delivery system containing the formulation of claim 1.

12. (Original) The ophthalmic delivery system of claim 11 comprising an ophthalmic tube having an ophthalmic tip and containing said aqueous gel.

13. (Original) A method of treating myopia comprising administering the formulation of claim 1 to the eye of a human individual, whereby myopia is treated.

14. (Original) The method of claim 13 wherein said human individual is a pediatric subject.

15. (Original) A method of making the formulation of claim 1 comprising autoclaving a mixture comprised of said gelling agent and water, sterile filtering a solution comprising said pirenzepine and water, and aseptically admixing them.

16. (Original) The method of the claim 17 wherein said autoclaving step is conducted under nitrogen.

17. (Currently amended) A formulation according to claim 1 wherein the formulation is selected from the group consisting of the formulations of ~~Table 1~~ the following table:

| <u>Ingredient</u>                    | <u>0.5% in mg/g</u> | <u>1.0% in mg/g</u> | <u>2.0% in mg/g</u> |
|--------------------------------------|---------------------|---------------------|---------------------|
| <u>Pirenzepine dihydrochloride</u>   | <u>6.3</u>          | <u>12.6</u>         | <u>25.2</u>         |
| <u>base equivalent</u>               | <u>5.0</u>          | <u>10.0</u>         | <u>20.0</u>         |
| <u>Hydroxypropyl Methylcellulose</u> | <u>20</u>           | <u>20</u>           | <u>20</u>           |
| <u>Sodium acetate</u>                | <u>0.40</u>         | <u>0.40</u>         | <u>0.40</u>         |
| <u>Benzalkonium chloride</u>         | <u>0.05</u>         | <u>0.05</u>         | <u>0.05</u>         |
| <u>Edetate disodium</u>              | <u>0.15</u>         | <u>0.15</u>         | <u>0.15</u>         |
| <u>Sodium chloride</u>               | <u>5.0</u>          | <u>3.5</u>          | <u>0.0</u>          |
| <u>Sodium Hydroxide to pH</u>        | <u>5.0</u>          | <u>5.0</u>          | <u>5.0</u>          |
| <u>Purified water to</u>             | <u>1.00 g</u>       | <u>1.00 g</u>       | <u>1.00 g</u>       |

18. (Original) A formulation according to claim 1 in sterile form.